Attorney Docket No. P149US01 Application No.: 10/538,745

REMARKS

I. Introduction

Reconsideration and further examination of this application is respectfully requested. The Office Action mailed on 01/04/2007 and the references cited have been carefully reviewed and considered.

II. Status of the Claims

Claims 185-248 were withdrawn in the 01/04/2007 Office Action. Applicant has cancelled these claims in this application without prejudice and may pursue them in a continuation/divisional application. Claims 249-298 have not been amended and are maintained as previously presented with the exception of Claim 275 which is currently amended to correct a typographical error.

III. Information Disclosure Statement

Copies of the three foreign patent documents listed on page 2 of the Information Disclosure Statement are included with this submission.

IV. Rejections under 35 U.S.C. § 102

The Examiner rejected claims 263, 268, 270, 288,293 and 295 under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 5,289,385 to Grandone (Grandone). According to the Examiner, Grandone teaches a biological sample analyzer with robotic pipette-booms that schedules sample operations, outputs data analysis results to data storage and prints test results. The Examiner explains that Grandone teaches allowing a user to enter a load list of samples, scheduling more than one operation, and performing those operations thereby anticipating the instant claims. Applicants respectfully traverse.

Applicant's claim 263 recites "automatically processing at least one biological sample arranged on a slide at least in part through operation of said robotic sample process functions sequencing through said scheduled plurality of sample process operations" ¹

A prima facie case of anticipation requires that a single publication teaches, either expressly or inherently, each and every element or limitation of the claim, including any functional

¹ A limitation of "<u>automatically processing</u> biological samples <u>arranged on a slide"</u> or equivalent is recited in all pending claims.

limitations. M.P.E.P. § 2131. Grandone does not disclose an analyzer that automatically processes biological samples arranged on a slide. Further there is no teaching or suggestion that the analyzer of Grandone could be modified to automatically process biological samples arranged on a slide. Grandone merely teaches an analyzer that mixes reagents with analytes in different reaction and separation wells and uses optical detection techniques to produce an analysis result which may be output to a printer or a computer interface after the analysis is completed.

In summary, since the analyzer taught by Grandone does not <u>automatically process</u> or even analyze samples <u>arranged on slide</u>, nor does it <u>store</u> important details of a significant number of a plurality of sample <u>process operations</u> <u>as such sample process operations occur</u>, Applicants respectfully request that the rejections of Claims 263, 268, 270, 288, 293 and 295 under 102(b) be withdrawn and that these claims be allowed.

V. Rejections under 35 U.S.C. § 103

A prima facie case of obviousness has three distinct requirements. First, the references must teach or suggest every claim element. M.P.E.P. §§ 2142 and 2143.03. Second, there must be a motivation to modify or combine the teachings of the cited references. M.P.E.P. §§ 2143 and 2143.01. Third, there must be a reasonable expectation of success in performing the modified or combined teachings of the references. M.P.E.P. § 2143.02. As pointed out above with respect to rejections under 35 U.S.C. 102(b), Grandone does not disclose an analyzer that <u>automatically processes</u> biological samples <u>arranged on a slide.</u> The Examiner, moreover, has failed to cite a prior art document that cures this deficiency. Therefore, Applicant requests that the rejections under § 103 be withdrawn for the reason described below.

Claims 249-251 and 274-276 were rejected in the Office Action of 01/04/2007 as unpatentable over Grandone in view of US Patent No. 5,473,551 to Sato et al. (Sato) and US Patent Application Publication 2005/10250211 to Reinhardt et al. (Reinhardt). Applicant respectfully traverses. Applicant submits that Reinhardt, which is a C-I-P, is not effective prior art to the instant claims because the matter cited by the Examiner was added to the C-I-P after Applicant's filing date as explained below.

According to the Examiner, "Reinhardt teaches that reagents can be delivered to workstation while replacing or replenishing reagents to the system (pars. 17, 45, 96). Therefore, the Examiner concludes it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include replenishing reagents, as taught by Reinhardt, because then throughput would have been increased (Reinhardt, par. 9)."

Careful reading and analysis of Reinhardt and the applications to which priority is claimed, reveal that the paragraphs in Reinhardt cited by the examiner (par 9, 17, 45, 96) that disclose replenishing of reagents is new matter added in the C-I-P filed on July 13, 2005. Neither Non-provisional US Patent Application 10/414,804 nor Provisional US Patent Application 60/372,506 disclose, teach, or suggest any of the cited material regarding replenishing of reagents.

In summary, nothing was disclosed in Reinhardt prior to the filing date of July 13, 2005, disclosing the monitoring replenishable supply information, automatically notifying at least one person of a potential need for a replenishable and "replenishing said replenishable supply in real-time concurrently with sample processing." Therefore the disclosure relied up on by the Examiner is not effective prior art to the instant claims.

Sato fails to overcome the deficiencies of Grandone and Reinhardt. Sato does not disclose or teach "monitoring operationally-influential exteriorly-consequential information, wherein said step of monitoring operationally-influential exteriorly-consequential information comprises the step of monitoring replenishable supply information; automatically notifying at least one person of a potential need for a replenishable supply in response to said step of monitoring operationally-influential exteriorly-consequential information; and replenishing said replenishable supply in real-time concurrently with sample processing." Thus the cited references fail to teach or suggest every claim element as required by the M.P.E.P. For at least these reasons, Applicant respectfully requests that the rejection be withdrawn and the claims 249-251 and 274-276 be allowed.

Claims 252-257 and 277-282 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of US Patent Application Publication 2003/10200111 to Damji (Damji). The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include monitoring statistical data, as taught by Damji since supply chains would have been more efficient (Damji, pars. 2-4). Applicants respectfully traverse.

First, Damji does not overcome the shortcomings of Grandone described above. Just as with Grandone, Damji fails to disclose, teach or suggest an analyzer that is capable of "automatically processing at least one biological sample arranged on a slide." Damji also does not disclose, teach or suggest monitoring information related to the processing of a biological sample arranged on a slide and monitoring historical or statistical <u>reagent usage</u>. Thus the cited references fail to teach or suggest every claim element as required.

Moreover, Damji relates to a different and remote technical field, namely the field of packaging and shipping of goods, and especially to processes for determining the optimal method and cost of packaging and shipping goods. Nothing in Damji suggests or provides motivation to combine the teachings of Damji with a laboratory analyzer as taught by Grandone. Likewise, nothing in Grandone suggests that Grandone might be combined with a method for packaging and shipping goods. Therefore, one of ordinary skill in the art of automatic biological sample analyzers as taught by Grandone would not be motivated to combine the teaching of Grandone with the teaching of Damji and the Examiner has failed to provide any requisite motivation for such a combination other than a conclusory statement of making supply chains more efficient. Thus, Applicants respectfully request that these rejections be withdrawn.

Claims 258, 259, 262, 269,271,283, 284, 287,294 and 296 were rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view' of US Patent Application Publication 200310163031 to Madden et al. (Madden).

According to the Examiner, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include a remote network connection for transferring data, as taught by Madden, because then analysis of results by other professionals would have been facilitated (Madden, pars. 2-9). Applicants respectfully disagree.

Madden does not overcome the shortcomings of Grandone in that Madden also fails to disclose, teach, or suggest automated processing of samples arranged on a slide as previously discussed. Thus, the cited references once again fail to teach or suggest every claim element as required by the M.P.E.P.

Claims 260 and 285 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of Madden as applied to claims 258 and 283 above, and further in view of US Patent Application Publication 200410220745 to Hosomi (Hosomi). Applicants respectfully disagree.

Neither Grandone, nor Madden, nor Hosomi disclose, teach or suggest "establishing a biological sample slide processing network dedicated to a stainer or a sample processing resource for integrity and security purposes; and accepting a prompt from a user to establish a remote access connection between said biological sample slide processing network and a remote location." Similarly, none of Grandone, Madden, or Hosomi disclose an "information access prompt element" as recited in claims 258 and 283. On the contrary, Madden teaches that the system "may be implemented over an open network (par 30). Moreover, Hosomi teaches away from accepting a user prompt to establish a remote access connection and teaches away from an information access prompt by teaching that it is advantageous to have remote connections established automatically without accepting an information accept prompt and without accepting a user prompt to establish a remote access connection. (par. 32) Any hypothetical combination of Grandone, Madden, or Hosomi would not serve to provide the integrity and security of a establishing a remote access connection to a dedicated stainer and sample processing network by accepting a user prompt or an information access prompt because Hosomi teaches that the instrument automatically connects to a server without authorization via a user prompt and Madden teaches using an open network. Thus, the cited references also fail to teach or suggest these additional claim limitations.

Therefore for at least these reasons, Applicants respectfully requests that these rejections be withdrawn.

Claims 264 and 289 were rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of US Patent Application Publication 200310032048 to Kim et al.(Kim). According to the Examiner, Kim teaches playing back the movement in a cell migration system (par. 215, 216). The Examiner further asserts it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer, as taught by Grandone, to include playback, as taught by Kim, because then analyzer steps could have been observed in real-time at a later time. Applicants respectfully traverse.

Kim also does not overcome the shortcomings of Grandone. Moreover, cited paragraphs 215 and 216 of Kim show that Kim merely teaches an observation system, that "may be used to observe and analyze the <u>real-time movement and behaviour of cells</u> as they respond to different and various stimuli." Nowhere does Kim disclose, alone or in combination with Grandone, recording or sequential playback of automated robotic sample process functions sequencing through a plurality of sample processing operations as described in Applicants' claims 264 and 289. Even if Kim is combined with Grandone there is no teaching of the playback capability of sample process operations because there is no disclosure that the observation system of Kim can observe or record anything other than movement of cells. Thus, once again the cited references fail to teach or suggest each claim limitation.

Thus, Applicants respectfully request that the rejection of claims 264 and 289 be withdrawn.

With regard to claims 265-267 and 290-292, the Examiner asserts that Foerster teaches altering the speed of video playback (Abstract). The Examiner also asserts that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer combination, as taught by Grandone and Kim, to include playback with altered speed, as taught by Foerster, because then the user would have been able to slow down the playback for better observation." Applicants respectfully disagree.

Foerster also does not overcome the failure of Kim and Grandon as described above.

For at least these reasons, Applicants request that the rejection of claims 265-267 and 290-292 be withdrawn.

Claims 272, 273, 297 and 298 were rejected under 35 U.S.C. 103(a) as being unpatentable over Grandone in view of Madden as applied to claims 271 and 296 above, and further in view of Kim. According to the Examiner, Kim teaches real-time playback of cell migration movement (par. 21 5). Also according to the Examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the analyzer combination, as taught by Grandone and Madden, to include playback, as taught by Kim, because then analyzer steps could have been observed in real-time at a later time. Applicants respectfully traverse.

As discussed above, Kim merely teaches an observation system, that "may be used to observe and analyze the real-time movement and behaviour of cells as they respond to different and

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various stimuli." Nowhere does Kim disclose either alone or in combination with Grandone, or

Madden, recording or sequential playback of automated robotic sample process functions

sequencing through a plurality of sample processing operations.

Consequently, Applicants respectfully request that the rejection of claims 272, 273, 297 and

298 be withdrawn.

VI. <u>Conclusion</u>

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this

application and the timely allowance of the pending claims.

As detailed in the calculations in the Claims Fee Calculation Table on the following page,

no additional claims fees are presently due and the appropriate form for payment by credit card is

enclosed.

If the Examiner believes a telephone conference would be useful in resolving any

outstanding issues, he is invited to call the undersigned at 970-204-7002.

Respectfully submitted,

Dated: March 9, 2007

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